Commonwealth of Virginia
Department of Health Professions
6603 Board Street Road, 5th Floor
Richmond, Virginia 23230

Date_____
Hours_____
Rev: 5/2005REV

WHOLESALE DISTRIBUTOR
INSPECTION REPORT

Name_____ License No. _____Exp Date_____

Street_____City_____State_____Zip_____

Telephone No_____ Fax No_____ Hours of Operation_____

Responsible Party _____

CSRC License No. _____ Exp Date _____ DEA No. _____ Exp Date _____

TYPE OF FACILITY

☐ **WHOLESALE DISTRIBUTOR** ☐ **Prescription Drugs** ☐ **Oxygen** ☐ **Other Medical Gases (Describe in Comments)**

INSPECTION TYPE

☐ **New** ☐ **Routine** ☐ **Change of Location** ☐ **Remodel** ☐ **Other _____**

DESIGNATIONS: C MEANS COMPLIANT, NC MEANS NON-COMPLIANT

FACILITY

	C	NC	
54.1-3430	__	__	Permit is displayed in a conspicuous place.

All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

110-20-670	__	__	Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations 21CFR205.50 (a)(1)
110-20-670	__	__	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions 21CFR205.50 (a)(2)
110-20-670	__	__	Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened 21CFR205.50 (a)(3)
110-20-670	__	__	Be maintained in a clean and orderly condition 21CFR205.50 (a)(4)
110-20-670	__	__	Be free from infestation by insects, rodents, birds, or vermin of any kind 21CFR205.50 (a)(5)

SECURITY

	C	NC	
110-20-670	__	__	Access from outside the premises shall be kept to a minimum and be well-controlled 21CFR205.50 (b)(1)(i)
110-20-670	__	__	The outside perimeter of the premises shall be well-lighted 21CFR205.50 (b)(1)(ii)
110-20-640 110-20-670	__	__	Areas in which prescription drugs are manufactured, stored, or kept for sale are held are restricted to only designated and necessary authorized personnel 21CFR205.50 (b)(1)(iii)
110-20-640	__	__	The holder of the permit shall provide reasonable security for all drugs in the restricted area
110-20-640	__	__	The holder of the permit shall not deliver any drug to a licensed business at which there is no one in attendance at the time of the delivery nor to any person who may not legally possess such drugs

Holder of the permit, except for distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking, subject to the following conditions: 21CFR205.50 (b)(2)&(3)

☐ **Alarm was tested at time of inspection**

110-20-640	__	__	Device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device
110-20-640	__	__	Installation shall be hard wired and both the installation and device shall be based on accepted burglar alarm industry standards

110-20-640	__	__	Device shall be maintained in operating order and shall have an auxiliary source of power
110-20-640	__	__	Device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated
110-20-640	__	__	Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business
110-20-670	__	__	When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. 21CFR205.50 (b)(3)

STORAGE

	C	NC	
110-20-670	__	__	All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
110-20-670	__	__	If no storage requirements are established for a prescription drug, the drug may be held at ``controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected. 21CFR205.50(c)(1)
110-20-670	__	__	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs 21CFR205.50(c)(1)
110-20-670	__	__	Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier 21CFR205.50(e)(1)

RECORDS

	C	NC	
Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information 21CFR205.50(f)(1)			
110-20-670	__	__	The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped 21CFR205.50(f)(1)(i)
110-20-670	__	__	The identity and quantity of the drugs received and distributed or disposed of 21CFR205.50(f)(1)(ii)
110-20-670	__	__	The dates of receipt and distribution or other disposition of the drugs 21CFR205.50(f)(1)(iii)
110-20-670	__	__	Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation. 21CFR205.50(f)(2)
110-20-670	__	__	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency. 21CFR205.50(f)(3)
Records of Drugs in Schedules I, II, III, IV & V (NOT APPLICABLE TO WHOLESALERS OF ONLY GASES)			
54.1-3404	__	__	Every inventory and other records required to be kept under this part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to Sec. 1305.13 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. CFR 1304.04(a)
54.1-3404	__	__	The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.
54.1-3404	__	__	Date of last inventory performed: _____ ☐ Opening or ☐ Closing of Business
54.1-3404	__	__	Inventories and records of Schedule II are maintained separately from all other records CFR 1304.04(f)(1)
54.1-3404	__	__	Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. CFR 1304.04(f)(2)
54.1-3404	__	__	The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the 1) date of selling, administering, or dispensing, 2) name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, 3) kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction

54.1-3404 __ __ The record of such drugs received shall in every case show the
1) date of receipt,
2) name and address of the person from whom received
3) kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture
4) date of such production or removal from process of manufacture

POLICIES & PROCEDURES

C NC

Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

110-20-670 __ __ A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate. 21CFR205.50(g)(1)

110-20-670 __ __ A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to (i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency; (ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or (iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design. 21CFR205.50(g)(2)

110-20-670 __ __ A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency. 21CFR205.50(g)(3)

110-20-670 __ __ A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs 21CFR205.50(g)(4)

COMPLIANCE (NOT APPLICABLE TO WHOLESALERS OF ONLY GASES)

C NC

110-20-670 __ __ Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration(DEA), and shall comply with all applicable State, local, and DEA regulations 21CFR205.50(i)(2)

Comments

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector Date Signature of Licensee Date